K032237

SEP - 5 2003

510(k) Summary
For N/T Protein Control LC

1. Manufacture's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:	Dade Behring Marburg GmbH Emil-von-Behring Str. 76 Marburg/Germany
Contact Information:	Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, Delaware 19714 Attn:Kathleen Dray-Lyons Tel: 781-826-4551
Preparation date:	July 18, 2003

2. Device Name/ Classification:

N/T Protein Control LC:	Quality Control Material (assayed)
Classification Number:	Class I (862.1660)

3. Identification of the Legally Marketed Device:

N/T Protein Control LC (K991704)

4. Device Description:
N/T Protein Control LC is a lyophilized control prepared from human urine and serum proteins with polygeline, rabbit albumin, and preservative. It is intended to be used as an accuracy control for the determination of human proteins in urine and CSF by immunonephelometry with the BN™ Systems and by immunoturbidimetry with the TurbiTimeSystem.

5. Device Intended Use:
N/T Protein Control LC is intended for use as an assayed accuracy and precision control for immunochemical determination of IgA, IgG and IgM in CSF, transferrin and α_1-microglobulin in urine, albumin and total protein in urine and CSF using the BN™ Systems and also for IgG in CSF and albumin in urine and CSF, using the TurbiTime System.

6. Medical device to which equivalence is claimed and comparison information:
The modified N/T Protein Control SL is substantially equivalent in intended use to N/T Protein Control LC currently marketed (K991704). The modified N/T Protein Control LC, like the current N/T Protein Control LC is intended to be used as quality control material to monitor the accuracy and precision of human urine and CSF protein assays on BN™ Systems and the TurbiTimeSystem

7. Device Performance Characteristics:

Stability:
Stability was evaluated according to in-house protocols and the control was found to be stable for at least 24 months at +2° to +8° C, as originally packaged and for at least 14 days at +2° to +8° C, once reconstituted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Kathleen A. Dray-Lyons
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P. O. Box 6101
Newark, DE 19714

Re: k032237
Trade/Device Name: N/T Protein Control LC
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: July 18, 2003
Received: July 21, 2003

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Device Name: N/T Protein Control LC

Indications for Use:

N/T Protein Control LC is intended for use as an assayed accuracy and precision control for immunochemical determination of IgA, IgG and IgM in CSF, transferrin and α_1-microglobulin in urine, albumin and total protein in urine and CSF using the BN™ Systems and also for IgG in CSF and albumin in urine and CSF, using the TurbiTime System.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109)

Over-The-Counter-Use ____ (Optional Format 1-2-96)

J P Reeves for T.J. O'Leary
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K032237